UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,676	06/21/2006	Louis H. Krut	26250002	2684

42624 7590 06/13/2007

DAVIDSON BERQUIST JACKSON & GOWDEY LLP
4300 WILSON BLVD., 7TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
HUANG, GIGI GEORGIANA	
ART UNIT	**PAPER NUMBER**
1609	

MAIL DATE	DELIVERY MODE
06/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,676	KRUT, LOUIS H.	
	Examiner	Art Unit	
	GiGi Huang	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The specification is objected to as it fails to comply with MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:

(1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."

(2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

Vague references are made to work by Wilkens, Krut, Schwenk et al., Tipton et al., and Higley et a. in the specification with no bibliographic information to direct where the information can be found.

Status of Application

2. Claims 1-10 are present for examination at this time.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Chong et al. (U.S. Pat. # 5,510,340).

Chong et al. teaches the composition and method of use of novel oxysterol compounds as antihypercholesterolemic agents.

The oxysterols are to be used as pharmaceutical agents for lower serum cholesterol. Chong goes on to teach the known relationship between atherosclerosis and cholesterol, where hypercholesterolemia is a primary risk factor for coronary heart disease. Oxysterols, which are formed by the oxidation of cholesterol, when administered are extremely useful in inhibiting the biosynthesis of cholesterol and thereby atherosclerosis (Abstract, Col. 1, lines 9-30, 40-45). This teaching indicated that the inhibition of delay of the crystallization of cholesterols is an inherent property of oxysterols (Col. 1, lines 40-55, Col 2, lines 6-68).

Chong teaches several classes of oxysterols, (Formula I-V, Col. 2) and their salts, that can be formulated at effective amount of drug with a pharmaceutical carrier, adjuvant, excipient, emulsifiers, buffers, flavorings, and the like. The oxysterols can be administered orally, parentally, and in various forms including pills, tablet, bolus, gels,

solutions, powders, and many other dosage forms. One skilled in the art as a result would immediately envision transdermal forms as it is known in the art and Chong addresses the fact that methods of preparing such dosage forms are known to one skilled in the art. He discloses that the techniques are readily available in Remington's Pharmaceutical Sciences (Col. 7, lines 28-68, Col. 8, lines 1-29, Claims 1-30).

Methods of use were taught via the administration of compositions to male Sprague-Dawley rats orally and the results were a reduction in cholesterol levels from about 40% to about 70%. Other methods of administration are immediately envisioned based on the teachings by Chong as other composition forms are taught.

As discussed above, transdermal forms and use would immediately be envisioned by one of skill in the art as directed by Chong. Chong claims the method of administering an effective amount of oxysterol, for lowering serum cholesterol (Col. 49, lines 20-68, Col. 50, lines 35-45, Table 2 and Table 3, Claim 31).

All the critical elements are taught by the cited reference and thus the claims are anticipated.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 1-10 are rejected under 35 U.S.C. 102(a) as being anticipated by Dudley (U.S. Patent Publication #2003/0153541).

Dudley teaches compositions comprising an LXR receptor modulator that is an oxysterol, with at least one catechin or lipid regulating agent (Abstract, Page 3, Paragraph 21).

Dudley teaches that naturally occurring oxidized derivatives of cholesterol (oxysterols) including 22(R)-hydroxycholesterol, 24 (S)-hydroxycholesterol, and 24,25(S)-epoxycholesterol activate the LXR's, leading to the lowering of serum cholesterol. This indicates that preventing or delaying the crystallization of cholesterol in an inherent property of oxysterols (Page 1, paragraph 8-9).

Dudley also teaches oxysterol compositions comprising other drugs, flavanoids, fatty acids, buffers, preservatives, carriers, and other excipients. He teaches several forms including capsule, tablet, pill, liquid, syrup, suspension, emulsions, gels, bolus, creams, powders, patch, and many more. Dudley also teaches several methods of administration corresponding to the different forms described in effective amounts for the reduction of cholesterol and disorders related to it (Page 5, paragraph 34-38, Page 6, paragraph 39-49, Page 7, paragraph 50-57, Page 8, paragraph 58, Claims1-2, 18-21, 59-68).

All the critical elements are taught by the cited reference and thus the claims are anticipated.

Conclusion

7. Claims 1-10 are rejected.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GiGi Huang whose telephone number is (571) 272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH

CECILIA TSANG
SUPERVISORY PATENT EXAMINER